ARMED SERVICES BLOOD PROGRAM ASSESSMENT TOOL FOR THE EVALUATION OF HOST NATION BLOOD SUPPLY

Version 1.0
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BACKGROUND INFORMATION:

Name of Assessor(s): _____

_____

_____

_____

Name of Facility: _____

Location of Facility: _____

Medical Director: _____

Director of Laboratory Services: _____

Blood Bank Supervisor: _____

Blood Bank Quality Assurance Supervisor: _____

Donor Center Supervisor: _____

Donor Center Quality Assurance Supervisor: _____

Number of blood units collected per year: _____

Number of transfusions per year: _____

Average Daily Inventory by blood type:

O Neg _____	O Pos _____
A Neg _____	A Pos _____
B Neg _____	B Pos _____
AB Neg _____	AB Pos _____

Name of any accrediting or certifying agencies: _____

_____

_____

_____

QUALITY ASSURANCE:

1. Quality System/Plan in place
2. Evidence that the Quality Plan is effective (audits, deviation reporting, assessments, etc.)
3. Procedures are in place and all appropriate personnel are trained with documentation
4. Competency Assessments are performed and documented
5. GMP or similar training is conducted. Frequency.
6. Effective error management system exists to include root cause analysis and tracking/trending
7. Mechanism to track the lot number and expiration date of all critical supplies (i.e. collection bags, sample tubes, frepp kits, etc.)
8. Document/change control system is implemented and followed
9. Review staff qualifications. List significant positions with qualifications

FACILITIES:

1. Work area is clear of clutter and adequate for workload
2. Adequate ventilation and utilities (i.e. water source, electricity)
3. Safety and Infectious Disease precautions are in place

TRANSFUSION SERVICES:

1. Specimen Collection
    a. Sample label includes patient's first and last name, identification number, date/time of collection and phlebotomist's initials
    b. Positive patient identification at collection and sampled at time of collection
    c. Label and request form are complete, accurate and legible. Information on label agree with request form

2. Pre-transfusion Testing/Compatibility
    a. Compatibility testing performed according to procedures
    b. Sample collected within 72 hours of scheduled transfusion if transfused within 3 months
    c. Sample tested for ABO/Rh and unexpected antibodies
    d. Samples stored refrigerated and sealed for 7 days post-transfusion

3. Policy for urgent release of blood products exists
    a. If recipient's ABO group unknown, group O RBCs issued
    b. If recipient's ABO group is determined on current sample, group specific or group compatible RBCs issued
    c. Compatibility testing is completed as soon as possible

4. Issue and Administration of Blood Products
    a. Blood is prescribed under medical direction
    b. Mechanism exists to positively identify blood component, intended recipient and special requirements
    c. Blood product inspected prior to issue for appearance and expiration date
    d. Mechanism for reissue of returned blood products
    e. Information identifying the product with the patient is matched in the presence of the recipient
    f. Identifying information remains attached to the product until transfusion is terminated
    g. Recipient is observed for adverse reactions during/after transfusion
    h. Transfusion record includes donor unit number, date/time of transfusion, pre and post transfusion vital signs, amount transfused, transfusionist's ID and whether or not there was a transfusion reaction
    i. Mechanism to trace donor unit through final disposition
    j. Procedure to response to any suspected transfusion reaction

5. Storage and Distribution
    a. Blood products are stored at temperatures demonstrated to be optimal
    b. Alarm systems are present and functional
    c. Storage temperature is recorded at least every 4 hours
    d. Blood products are transported in a manner consistent with standards
    e. Procedure for blood product storage in the event of a disruption in power

BLOOD DONOR CENTER:

1. Donor Suitability
    a. Positive donor identification that links donation to donor record
    b. Privacy and confidentiality is ensured for donor interview
    c. Donors informed of importance of not donating if their blood is not safe
    d. Review criteria for selection of donors
    e. Obtain a copy of their Blood Donor Record, if possible
    f. Obtain a copy of their oral questions, if possible

2. Component Collection
    a. Mechanism to ensure records, products and samples are traceable to one donor
    b. Manner ensures sterility of the venipuncture site and collected components
    c. Provisions for potential adverse reactions of donors
    d. Volume of blood collected is appropriate for amount of anticoagulant
    e. Collected units appropriately stored for components to be manufactured

3. Component Processing
    a. Sterility of components, aliquots of components and pooled components are maintained though out processing
    b. Procedures and practices address breakage of seal during processing
    c. Storage periods and conditions are established/maintained based on processing requirements
    d. Incompletely tested and unsuitable units are quarantined
    e. Plasma components are separated within appropriate time frame
    f. Sampling of platelet units are tested and processed appropriately (review QC if permitted)
    g. Criteria exist for accepting products prior to release
    h. Procedure for performance and review of quality control, corrective action taken when appropriate

4. Testing
    a. Samples are collected at the time of donation in a manner to ensure integrity and traceability to donor
    b. ABO, Rh and infectious disease testing is performed according to manufacturer's directions (document the types of infectious disease testing performed, methodology and test kit utilized)
    c. Methods used to detect unexpected antibodies is known to demonstrate clinically significant red cell antibodies
    d. Plasma containing blood components are labeled with the identity or any detected antibody
    e. Lot release process exists that establishes the validity of all test results and ensures that all testing discrepancies are resolved prior to release of products

f. Units with incomplete or invalid test results or other discrepancies are quarantined pending final resolution
g. Methods exist for emergency release of incompletely tested components
h. Review criteria for donor deferral based on testing (obtain testing deferral algorithm, if possible)

5. Labeling
    a. Method of unit and components identification and tracking to ensure unsatisfactory units are not released
    b. Quarantine and lot release processes exist
    c. Second check to ensure correct label information and reverification after component modification
    d. Unique identifier from collecting facility remains on the unit and allows for tracking of unit from cradle to grave
    e. Label of pooled components contain: name of pooled component, final volume, name of facility, and unique identifier
    f. Products released under emergency release are appropriately labeled

6. Storage/Distribution
    a. Refrigerators are monitored for proper temperature
    b. Components are stored and transported to ensure optimal function and safety
    c. Temperature of refrigerators, freezer, and platelet incubators are monitored continuously and recorded at least every 4 hours
    d. Transportation of components are maintained within appropriate temperature range
    e. Component expiration date/time are appropriate for collection, processing and storage

7. Adverse Effects
    a. Verify notification by transfusion services when serious complications with transfusion occurs (obtain a copy of their suspected transfusion reaction criteria and a suspected transfusion reaction workup)
    b. Look back investigations are performed and proper notification given